



United States Department of Agriculture

March 13, 2019

Charles Smith, Acting Director
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs, Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: USDA Comments on the Registration Review Draft Risk Assessment of Triphenyltin Hydroxide (TPTH); EPA-HQ-OPP-2012-0413.

Dear Mr. Smith:

Thank you for the opportunity to comment on EPA's Draft Risk Assessments for the registration review of the fungicide, triphenyltin hydroxide (TPTH), in a memorandum dated January 29, 2019 that authorized the extension of the public comment period for Q4 FY2018.

USDA values the benefits of the agricultural uses of triphenyltin hydroxide (TPTH), principally used by sugar beet and pecan growers in their disease management and fungicide resistance management strategies. The advantages realized by the application of TPTH and its unique fungicidal properties are characterized in the following overview of disease management challenges:

Sugar Beets

Causal Pathogenic Fungus of Cercospora Leaf Spot (CLS) in Sugar Beets is Aggressive

C. beticola, the causal fungus of Cercospora leaf spot (CLS) in sugar beets, is able to survive under adverse environmental conditions via overwintering structures (e.g., stromata) in infected crop residue. Also, spores produced on these survival structures serve as primary inoculum during the next cropping season. *C. beticola* inoculum left on the soil surface survives for about 22 months while those buried at a depth of 10-20 cm remain infective for about 10 months. Wind is considered the major factor for dispersal of inoculum while the leaf serves as the primary infection site of *C. beticola* (Khan et al., 2008).

C. beticola inoculum that overwinters on plant debris and the soil from previous crops is the source of infection for the current growing season. Many growers practice a four-year crop rotation and could expect disease build-up of infective spore populations, and corresponding increase in the risk of an epidemic necessitating the use of TPTH in their disease control program (Secor et al., 2010).

Further, the causal fungus is polycyclic in nature and is known to complete more than one generation per crop growth season. With each disease cycle, the amount of inoculum or infective

propagules increases exponentially, causing an epidemic. Hence, fungicides are the dominant control tactic to reduce the rate of CLS progression (Knight et al., 2018).

CLS is the Most Damaging Disease in Sugar Beets Reducing Yield and Quality

CLS is the most economically damaging foliar disease of sugar beets, not only in the U.S., but worldwide. In the larger sugar beet growing states in the U.S., such as MN and ND, losses from CLS in 1998 were estimated at \$113 million due to poor disease control. The result was not only reduced yield, but also an increase in fungicide application costs. Under moderate to heavy CLS disease pressure, losses of about 30-48% in recoverable sucrose were incurred, and relative revenue losses have been reported as high as 43%. CLS-infected sugar beet also had increased concentrations of impurities, resulting in higher processing costs and reduced extractable sucrose. Further, roots of diseased plants do not store well for longer periods compared to healthy roots when stocked in ventilated or frozen piles (Khan et al., 2007; Khan and Smith, 2005).

In a study conducted by Khan and Smith (2005) in Crookston, MN, TPTH in an alternating spray schedule with a triazole (tetraconazole), a triazole + a strobilurin (trifloxystrobin) or a benzimidazole (thiophanate-methyl) + a dithiocarbamate (mancozeb) significantly reduced the severity of CLS and resulted in significant increases in root yield, sucrose yield, and sucrose concentration (Table 1).

Table 1. Cercospora leaf spot control of sugarbeets with TPTH in spray programs in Minnesota, 2000 (Table modified from Khan and Smith, 2005) ^a

Treatment^b	Application Number	CLS^c	Root Yield (Mg/ha)	Sucrose Yield (kg/ha)	Sucrose Concentration (%)
<i>Breckenridge, MN</i>					
Tetraconazole Thiophanate-methyl + Mancozeb TPTH	1, 4 2 3	1.8 e- f	63 b-e	10898 a-c	18.9 ab
TPTH Tetraconazole	1, 3 2, 4	2.9 c- e	63 b-e	10850 a-c	19.0 a
Propiconazole + Trifloxystrobin TPTH	1, 3 2, 4	2.7 c- f	62 c-e	10813 a-c	19.1 a
Tetraconazole TPTH	1, 3 2, 4	3.4 c	65 a-d	10713 a-c	18.2 ab
TPTH	1-4	5.5 b	61 de	9925 cd	18.1 ab
Non-treated Control		7.9 a	58 e	9283 d	17.9 ab
<i>Crookston, MN</i>					
Tetraconazole Thiophanate-methyl + Mancozeb TPTH	1, 4 2 3, 5	2.8 d- f	61 a-d	10144 a-d	17.9 ab
TPTH Tetraconazole	1, 3, 5 2, 4	3.2 cd	56 e	9055 f	17.5 b

Propiconazole + Trifloxystrobin TPTH	1, 3, 5 2, 4	2.0 fg	59 b-e	10053 b-e	18.2 ab
Tetraconazole TPTH	1, 3, 5 2, 4	2.8 d- f	57 de	9578 d-f	18.0 ab
TPTH	1-5	4.8 b	56 e	9263 ef	17.7 ab
Non-treated Control		7.5 a	43 f	6690 g	16.7 c

^a Means followed by the same letter do not significantly differ (P=0.05, Student-Newman-Keuls)

^b Treatments were applied at approximately 14-day interval

^c Cercospora leaf spot (CLS) measured on KWS scale 1-9 (1=no leafspot; 9=most leaves dead with regrowth of new leaves) rated 22 September

Primary Fungicide Applied Under Heavy CLS-Disease Pressure

Four to five genes are responsible for CLS resistance. However, combining a high level of genetic resistance to *C. beticola* while achieving high yield is difficult to obtain. Most commercially available sugar beet cultivars have only moderate levels of CLS-disease resistance, requiring fungicide applications for adequate protection against the CLS pathogen (Khan and Smith, 2005).

TPTH is recommended as the primary fungicide of choice in its application by growers and cooperatives (Khan et al., 2007), especially in the southern part of the Polk-Norman county line of MN and ND where disease pressure is known to occur at higher levels. Application of fungicide was based on the observation of early symptoms of CLS or the occurrence of a disease level of 0.01% which is equivalent to one lesion per lower leaf.

Unique Fungicide in FRAC Code 30 for CLS Management

The five major groups of fungicides with different modes of action that are registered for the management of CLS in sugar beets include: methyl benzimidazole carbamates or MBCs (e.g., thiophanate-methyl, FRAC Code 1), quinone outside inhibitors or QoIs/strobilurins (e.g., trifloxystrobin, pyraclostrobin, azoxystrobin, FRAC Code 11), demethylation inhibitors or triazoles (e.g., tetraconazole, fenbuconazole, prothioconazole, difenoconazole + propiconazole, flutriafol; FRAC Code 3), dithiocarbamates (e.g., mancozeb, FRAC Code M3), and organotin compounds/tri-phenyltin compounds (fentin hydroxide/tri-phenyltin hydroxide or TPTH, FRAC Code 30). Premix formulations with two different fungicide chemical groups are also labeled such as azoxystrobin (FRAC Code 11) + flutriafol (FRAC Code 3), and tetraconazole (FRAC Code 3) + TPTH (FRAC Code 30).

The bulk of registered chemistries belong to the triazoles (FRAC Code 3) are considered as medium risk fungicides to evolve resistance followed by the strobilurins class (FRAC Code 11), which is regarded as being at high risk for resistance evolution. The MBCs are also acknowledged to be fungicides with a high risk of resistance evolution. TPTH is considered to be a low to medium risk fungicide, intrinsically, while the dithiocarbamates are considered as low risk. Loss of TPTH in the management of fungicide resistance will provide growers with fewer crop protection options, especially with fungicides recognized as having a lower risk of developing resistance. TPTH is the sole fungicide that inhibits the enzyme ATP synthase in the oxidative phosphorylation of fungal respiration process. TPTH provides growers with the flexibility to be utilized in their weather-based decision-making, as it can be applied at any growth stage. Further, it can be applied

either as a tank mix with tetraconazole or as an alternating fungicide with high risk fungicides such as strobilurins, MBCs and other triazoles.

Preferred Fungicide in Resistance Management

The dearth of highly effective fungicides for disease control strategies with the concomitant evolution of fungicide-resistant *C. beticola* populations, necessitates the development and deployment of effective fungicide resistance management programs. Rozenzweig et al. (2015) emphasized that when sugar beet growers decide to continue using fungicides with a high risk of resistance evolution, such as strobilurins/QoIs (FRAC Code 11) and methyl benzimidazole carbamates/MBCs (FRAC Code 1), it is recommended that the following strategies be observed: 1) continue to monitor field populations of *C. beticola* for mutations responsible for fungicide resistance such the molecular approach of PCR-RFLP analysis; 2) limit the number of fungicide applications during a growing season; 3) never apply consecutive applications of fungicides with the same mode of action; 4) apply high risk fungicides early in the crop growing season either in alternation, tank-mixture, or when available, as pre-pack mixes with compounds of different mode of actions; and 5) never use fungicides as a curative treatment.

Khan et al. (2007) indicated that from 1999 to 2002, sugar beet growers had been alternating TPTH with another fungicide of a different mode of action, such as tetraconazole (FRAC Code 3), to effectively mitigate CLS and consequently, reduced the frequency of application in the southern county line of MN and ND from 3.74 applications to 2.8 applications. This alternating spray program also drastically reduced the production of secondary infection or inoculum in sugar beet fields.

Secor et al. (2010) demonstrated that a consistent and efficacious fungicide program involving a three-way spray program was shown with the use of only one triazole fungicide per season, one QoI or strobilurin fungicide per season and TPTH at full label application rates. Application of these fungicides as a protectant, and observing better leaf spray coverage, provided superior control of CLS. The first fungicide application is implemented when first symptoms were observed, and subsequent applications made on a 14-day spray interval. Fungicide applications are deployed not only on the observance of symptoms, but also on the daily infection values (DIV), involving favorable temperature and relative humidity, that is forecasted over a 48 hour period. Not only should fungicides be rotated within a growing season, but also between growing seasons. The resistance management program in sugar beet production areas has included the use of fungicide sensitivity maps to aid growers in the selection of an appropriate fungicide in different counties of MN and ND.

Standard Fungicide CLS Management

Secor et al. (2010) noted that resistance to TPTH was first reported in 1994 and eventually, the loss of control in the field continued until 1998. However, at the start of 1999, the incidence of *C. beticola* fungal isolates that were resistant to TPTH declined significantly from about 65% to 0% in 2008. During this 10-year period from 1998 to 2008, reduction in resistance coincided with the registration of new fungicides such as tetraconazole (FRAC Code 3) in 1999, trifloxystrobin (FRAC Code 11) in 2002, and pyraclostrobin (FRAC Code 11) in 2003.

Further, Secor et al. (2010) observed that the number of TPTH applications was reduced from an average of 2.14 in 1998 to less than 1.0 from 2001 through 2008. This reduced number of TPTH applications resulted in reduced selection pressure on *C. beticola* isolates, as well as the reduced ability of TPTH-resistant isolates to survive under adverse environmental conditions in the Red River Valley production area. Regardless of the mechanism, TPTH remains the most effective fungicide for managing CLS in ND and MN and is a critical partner for managing resistance along with other fungicides with different modes of action. Resistance monitoring and field fungicide efficacy trials in grower fields all attest to the field performance of TPTH for CLS control over many years.

A Special Local Need Requested by Sugar Beet Growers in ND, MN and MT

Recently, TPTH was granted a Section 24c registration for use on sugar beets to control *Cercospora* leafspot in the states of ND, MN and MT by ground and aerial application methods. In the states of MN and MT, wettable powder formulation of TPTH was applied at the recommended use rate of 2.5-5.0 oz per acre, on a 10-14 day spray interval, and with a limit of 15 oz per acre per season. However, ND utilized the flowable formulation at a rate of 4-8 fl. oz per acre; not to exceed 24 fl. oz per acre per season. The lower rate is utilized for protective sprays and the higher rate for high infection period occurring at the later phase of the growing season. The PHI is 7 days with a precautionary statement of “Do not graze or feed beet tops to livestock”.

Pecans

Pecan Scab Fungus is Highly Adaptable

V. effusa, the causal fungus of pecan scab (previously described as *Fusicladium effusum*), poses the greatest risk of resistance evolution, as evidenced by the ability of the fungal pathogen to adapt and overcome several resistant cultivars over time. The basis of adaptability can be attributed to the pathogen’s high genetic variability, high reproductive capacity, high potential for genotype/gene flow, high mutation rates, and large effective fungal population sizes. Moreover, the inoculum is easily dispersed over long distances and eventually recombines into virulence genes. Thus, pecan growers are challenged in managing pecan scab due to the pathogen’s high risk to evolve resistance. Knowledge of the genetic diversity and population genetic structure of *V. effusa* can help guide a range of disease management strategies for growers and can also provide relevant information on reproduction of the pathogen and spread of the disease, particularly the sources of inoculum and dispersal processes (Bock et al., 2017; Bock et al., 2018).

Pecan Scab is a Widespread and Destructive Disease in the Southeast

Pecan scab causes significant yield loss, exhibiting a reduction in the size and quality of nutmeats. Investment in scab disease control is a recurrent annual cost to the growers. For example, in the state of GA, in 2013, a 15% reduction in crop value due to pecan scab led to an estimated total economic loss of \$78.7 million (Bock et al., 2017).

Pecan scab is a widespread and destructive disease. The pathogen is spread primarily through air- and splash-borne infective propagules (conidia). The quantity of conidia produced increases during the growing season as the disease progresses, and when existing environmental conditions are favorable for repeated cycles of dispersal and infection. In addition, after a rainfall event, conidia

are dispersed via air currents, with localized dispersal occurring through rain splash. Periods with temperatures in the range of 15-25C and an occurrence of leaf wetness of 24-48 hours are conducive for pecan scab development. The polycyclic nature (secondary inoculum produced and potential secondary dispersal of inoculum) of pecan scab, and the period over which leaves and fruit remain susceptible, makes it a major re-occurring threat to pecan production, as cycles of infection can result in rapid build-up of inoculum and subsequent disease epidemics (Bock et al., 2013; Bock et al., 2017).

Rainfall events occur frequently in the Southeast typified by hot, humid and wet summers. Historically, the climate in GA features abundant rainfall during the growing season, approximately ≥ 570.5 mm of rain between April through August. This coincides with the period when pecan foliage and fruit are at a high risk of infection from the pathogenic fungus. This rainfall pattern is typical of other Southeastern states where pecan and scab disease epidemics are common, such as AL, AR, LA, MS, OK, NC, SC, TN, and eastern TX (Bock et al., 2017).

In addition to the favorable climatic conditions in the Southeast, the overall proportion of resistant cultivars planted in commercial orchards remains low. Pecan growers have continued to plant cultivars that are susceptible to scab due to the availability of existing germplasm as well as the highly valued nut characteristics or other horticultural traits.

Unique Fungicide in FRAC Code 30 for Pecan Scab Management

The seven major groups of fungicides registered for the management of pecan scab include quinone outside inhibitors or strobilurins (FRAC Code 11), triazoles/demethylation inhibitors (FRAC Code 3), MBCs (FRAC Code 1), plant activators (FRAC Code P7), dithiocarbamates (FRAC Code M3), guanidines (FRAC Code U12), and organo tin compounds/tri-phenyl tin compounds (FRAC Code 30). Those major chemical groups regarded as high risk fungicides belong to FRAC Codes 1, 3, and 11 whereas those chemistries with low to medium risk belong to FRAC Code P7, M3, U12, and 30. Since TPTH is the sole fungicide in FRAC Code 30, no cross-resistance to other registered fungicides is expected. Loss of TPTH use would not only provide pecan growers with fewer low risk fungicides to rotate or tank mix in their fungicide resistance management strategies, but would also reduce the number of efficacious fungicides to select from to effectively control pecan scab (Wells, 2019).

Critical Component in Fungicide Resistance Management

Since the introduction of TPTH in the 1960s, TPTH has been an outstanding protectant fungicide in controlling pecan scab. According to Bock et al. (2017), the frequency of resistance in a pathogen population with the use of TPTH increased much more gradually over a period of 20 years or more and may never approach to 100% compared to other high risk fungicides, such as the strobilurins and MBCs. Thus, pathogen populations of *V. effusa* often exhibit a wide range of sensitivities or susceptibilities to TPTH.

The risk of resistance evolution is greatest for fungicides with a single-site mode of action such as the DMIs, MBCs and QoIs/strobilurins compared with the multi-site mode of action chemistries such as TPTH, dodine, ziram, and phosphites.

Proven and Standard Fungicide to Control Pecan Scab

In a 2016-2017 efficacy orchard trial in Ty Ty, GA, TPTH, applied either as a single fungicide or as a tank-mixture with tebuconazole, significantly reduced the incidence and progression of leaf scab disease on a 14-day spray interval (Standish, Brenneman and Stevenson, 2018). Likewise, the stand alone or tank-mixture of TPTH significantly reduced the severity of nut scab. Overall, TPTH-treated trees consistently provided lesser leaf and nut scab than the non-treated control trees in a moderate to severe scab pressure (Standish, Brenneman and Stevenson, 2018).

In a field efficacy trial conducted by Bock et al. (2012), TPTH applied either as a part-season treatment (6 fungicide applications) or as a full-season treatment (8 fungicide applications), significantly reduced scab severity on pecan fruit in a mixed-cultivar orchard in Byron, GA in comparison to the untreated control (Table 2). Moreover, TPTH applied in either part or season-long programs gave significant increases in yield with respect to fruit weight, nut volume and kernel weight compared with the non-treated trees (Table 2).

Table 2. Efficacy of TPTH applied part-season and full-season for controlling scab on pecan foliage and fruit in 2010 in a mixed-cultivar orchard in Byron, GA (Table modified from Bock et al., 2012)

Fungicide^a	% Leaflet Area^b	% Fruit Area		Fruit Weight (g fresh)	Nut Volume (cm³)	Kernel Weight (g)
	<i>Jun 11</i>	<i>Jul 7</i>	<i>Oct 15</i>			
Untreated Control	0.8 b	11.0 c	59.3 b	20.2 a	8.2 a	2.81 a
TPTH (PS)	0.4 a	2.9 a	25.6 a	27.2 c	9.7 b	4.14 c
TPTH (FS)	1.3 c	1.4 a	24.7 a	25.0 bc	9.4 b	3.67 b

^aRate for TPTH=0.90–1000L/ha. PS (part-season) treated-trees received six applications at about 2-week intervals between April 21 and July 16. The FS (full-season) treated-trees received two additional sprays on Aug 5 and 27.

^bDisease severity was assessed visually for the percent area of the leaflet or fruit surface infected, with treatment means based on two replicate trees for each treatment. Yield variable means based on 10 fruit from two replicate trees for each treatment.

Human Health Assessment (Drinking Water):

USDA understands and appreciates that OPP policies dictate a high level of conservatism for the screening-level assessment of drinking water concentrations for inclusion in HED dietary assessments. We note that given the high soil binding affinity for this chemical, EPA projects no groundwater issues for this chemical, under screening level assumptions about usage and high vulnerability of wells.

With regard to surface water concerns, USDA requests that OPP engage in further model input refinement for estimation of surface water EDWCs, as has been done recently for other chemical cases, such as aldicarb. USDA is unclear on why the Orchard Barton Spring Salamander (OBSS) scenarios were used for this assessment rather than the standard Georgia pecan scenario developed by EPA. We note that EFED states that the OBSS scenario does not take into account proximity to drinking water intakes and urge EPA to consider an approach that does seek to identify real-

world-relevant scenarios for vulnerable surface water intakes, since this is the most likely route of exposure for drinking water.

While USDA appreciates that a somewhat refined regional PCA of 0.23 was chosen based on the limited suite of registered uses, USDA notes that TPTH is not registered on all vegetables and tree fruits. To the extent possible, EPA should seek out information on the actual percentage of watershed areas in Georgia that are occupied by pecans alone, given that this is the use scenario with the highest likely usage both in terms of application rates, numbers of application, and the highest overall percent of crop that is treated with TPTH, and also the area driving the potential surface water exposure estimates (i.e., because of more frequent rainfall in Georgia production areas than in the western U.S.). It is unclear from the current assessment whether the regional PCA of 0.23 was chosen because it was the larger of two available options (i.e., OBSS vs. GA-pecan), or whether it truly reflects an estimate for Georgia pecans. Regional refinements focusing on the most vulnerable watersheds could potentially refine exposure estimates significantly for this highly important fungicide.

USDA urges EPA to also consider incorporation of average PCT for additionally refined PCA calculation or characterization, at least for determining the 30 year average exposure that is used for assessing cancer risk. USDA concedes that such a refinement may not be appropriate for determining the 1-in-10 year acute EDWC. USDA also appreciates that EPA presented a sensitivity analysis based around average DT-50 values for characterization consideration. While EPA states this is not typically used in assessment, USDA urges EPA to explain why such a refinement would not be a valid approach, particularly for simulating the most likely real-world exposure estimates that are considered over a 30 year period as is done for the cancer portion of EPA's human health risk assessment. Finally, USDA urges EPA to consider if a time series analysis could be conducted to assess the relative likelihood over time of problematic EDWC occurrence, given the low frequency of runoff/erosion events that would contribute to surface water exposure—particularly for areas close to actual vulnerable water intakes in small watersheds. Such an approach could be used to construct an EDWC estimate distribution over time, which could be used for characterizing the relative likelihood of various exposure estimates on a regional or exposed human population level.

USDA suggests that given the number of uncertainties identified by EPA regarding stability, the binding affinity to activated sludge, and the efficacy of various municipal water treatments to removing organotin compounds, etc., EPA's exposure likelihood estimates should also consider the lack of problematic detections of TPTH in available surface water monitoring data. While USDA understands that the lack of positive monitoring detections does not completely preclude the possibility of TPTH presence in surface water, the numerous identified uncertainties surrounding the fate and degradation characteristics of this chemical, combined with the likely limited usage footprint of TPTH on pecans (i.e., usage on pecans grown east of the Mississippi is the most likely surface water exposure scenario) should be considered qualitatively when assessing the likelihood of human drinking water exposure.

Ecological Risk Assessment:

USDA appreciates that the preliminary ecological risk assessment for TPTH includes some very helpful usage and risk characterization information for the identified risks of concern. We particularly appreciate EPA's presentation and consideration of species sensitivity distributions, variable application rates, use by use comparisons, and LOAEC vs. NOAEC effects endpoints for characterization of risks to aquatic taxa. We also appreciate the discussions around upper-bound vs. mean Kenaga exposure estimates and consideration of dietary intake assumptions, in addition to the aforementioned characterizations for risks to birds and mammals. USDA understands that particularly for chronic terrestrial vertebrate exposure scenarios, TPTH presents risk managers with some challenging risk scenarios, given that risks of concern involve reproductive effects.

In developing risk management strategies, USDA urges EPA to consider feasible and reasonable options to reduce off-site movement from treatment sites to minimize non-target exposure potential. It is critical that any potential drift mitigation options be considered in a practical way that retains the efficacy and utility of TPTH for users with critical disease management needs, particularly for pecans and sugar beets. While droplet size restrictions may be a feasible approach for mitigating drift, USDA urges EPA to consider any available data on how droplet size affects the fungicidal efficacy of TPTH, which works by contact only, with no systemic uptake by plants. For example, if droplet size restrictions drive growers to use higher application rates to compensate for lost efficacy, this would be a counter-productive outcome for risk reduction efforts. USDA stands ready to assist with getting expert feedback on the potential efficacy impacts of spray droplet sizes ranges for TPTH and to provide any additional feedback on the substantial agricultural benefits for this important fungicide.

Fish, Aquatic Invertebrates, Aquatic Plants:

USDA notes that acute exceedances for aquatic taxa are generally driven by the use on pecans. We note that additional characterization (for either acute or chronic exceedances for aquatic taxa) might be accomplished by considering the potential infrequency of EEC values exceeding risk thresholds, based upon time series analysis. Particularly for events driven by runoff events, consideration of the relative likelihood of rain events coinciding with applications may shed light on the real-world potential probability of risk exceedances. USDA appreciates the helpful characterization that is already offered around the risks to these taxa, which should prove helpful to risk managers seeking to contextualize such risks in light of the very high benefits of TPTH usage, particularly for pecans and sugar beets.

Terrestrial Invertebrates (Bees):

USDA notes that TPTH is not expected to be acutely toxic to bees and thus is not expected to be subject to EPA's published policy for protection of pollinators on bee pollinated crops for acutely toxic pesticides. USDA acknowledges that questions remain regarding adult chronic and larval (both acute and chronic) bee toxicity due to outstanding bee data requirements. USDA concurs with EPA's statement that oral exposure through pollen and nectar is highly unlikely for the remaining registered crops, given the lack of attractiveness (pecans) and the fact that none of the registered uses are for crops where honey bees are expected to be present, either for pollination or honey production.

Birds and Mammals:

USDA appreciates EPA's numerous characterizations regarding the chronic risk exceedances for mammals. These included consideration of LOAEC vs. NOAEC values for the effect endpoints, consideration of mean Kenaga exposure estimates vs. upper bound estimates, consideration of typical/lower application rates + single applications, and a dissipation half-life of 3-8 days instead of the standard default 35 days. USDA notes that dietary consumption assumptions for chronic exposure are still very high and that many birds and mammals are likely to have a more diverse and wide-ranging spatial foraging pattern, and are unlikely to spend multiple weeks consistently feeding in treated fields. This would be particularly true for the likelihood of feeding on treated crop foliage for tree nuts such as pecans.

USDA notes that on the whole, the most problematic risks of concern for vertebrates, when considering available refinements and characterizations, are chronic risks related to reproductive effects and not acute toxicity risks. We urge EPA to consider the relatively limited spatial footprint of TPTH usage (for pecan production in particular), with regard to the likelihood and potential for the most likely problematic ecological impacts. We also urge EPA risk managers to consider and prioritize what are the most important non-target protection goals (particularly considering risks on-field vs. off-field), and to consider how these goals would relate and compare to the substantial agricultural benefits of TPTH as a lynchnip disease management tool for crops such as pecans and sugar beets.

USDA looks forward to working with EPA as the draft risk assessments proceed into the proposed interim decision stage in the registration review of TPTH. If you need additional information, please do not hesitate to contact me and will be glad to assist.

Sincerely,



Elizabeth Hill,
Acting for Sheryl Kunickis, Ph.D.

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